

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR - 5 1998

Jeffery K. Van Horne  
Environmental Engineer  
ISK Biosciences Corp.  
2239 Haden Road  
Houston, TX 77015

Dear Mr. Van Horne:

This is in response to your letter of October 29, 1997 in which you request an interpretation of the PCB regulations at 40 CFR part 761, in particular, your concerns focus on the management of wastes and products derived from an "excluded manufacturing process" as defined under 40 CFR 761.3. As background, your letter indicates that ISK operates two processes that have been in existence since prior to 1984, each of which qualify as an excluded manufacturing process, and for which you have submitted certification for the products pursuant to 40 CFR 761.185. Your letter also states that in the future you may need to increase production of one of the products and/or suspend production of one of the products. Your letter raises six "Items" for discussion, each of which will be summarized and responded to accordingly.

**Item Number 1: Reporting Criteria at 40 CFR 761.187**

You seek confirmation under this section that the intent of this reporting requirement is to provide the EPA with a means of accounting for major releases of inadvertently generated PCBs and not intended to limit production and/or the amount of inadvertently generated PCBs. Therefore, if ISK increases production of its products and thus increases the amount of inadvertently generated PCBs over the established pound limit for the Houston, Texas site, and reports to EPA under 40 CFR 761.187, there will be no adverse consequences to ISK's business for making such a notification, that no public announcements will be made by EPA regarding such a notification, and that EPA retains the information on file for data recordation and future assessments of the PCB rules.

**Response to Item Number 1:**

The intent of the recordkeeping, certification, and reporting requirements under 40 CFR

761.185, 187, and 193 was to use this information to develop an enforcement strategy and

SYMBOL	compliance monitoring program as well as to track the amount of inadvertently generated PCBs						
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FILES:NPCD/FOB CHRON READING/SUBJECT: excluded manufacturing process / reporting

produced. ISK may continue to take advantage of the exclusions as an excluded manufacturer as long as the basic requirements of 40 CFR 761.1(b) are met, the definition of "excluded manufacturing process" at 761.3 is adhered to, and the provisions of 761.185, 187, and 193 are complied with as appropriate. Reporting data to EPA pursuant to the provisions of 40 CFR 761.187 should have no adverse consequences to ISK's business. EPA does not announce the receipt of the information, but the information is available for public review in the TSCA Public Docket.

#### **Item Number 2: Definition of "Site" at 40 CFR 761.187**

It is your understanding that the term "site" at 40 CFR 761.187 refers to a manufacturing facility which may contain several production units such as ISK's Houston, Texas facility. In determining the pound baseline for which reporting to the EPA is triggered, the total PCB pound baseline is calculated by taking the sum of the rated pound capacity as of October 1, 1984 of the two manufacturing processes (each which produce a product subject to the excluded manufacturing process exemption) and multiplying by 0.0025%. This calculated PCB pound amount remains as the baseline for reporting for the site, regardless of future increases or decreases in production. Further, it is your understanding that the PCB pound limit is site specific, not product or process specific.

#### **Response to Item Number 2:**

You are correct in your understanding of the term "site" and how to calculate whether you have exceeded the 1984 pound baseline for which reporting to EPA is triggered under 40 CFR 761.187. The PCB pound limit calculation is site specific and not process or product specific. It is based on the "total quantity of PCBs in products from excluded manufacturing processes leaving any manufacturing site in any calendar year, when such quantity exceeds 0.0025 percent of that site's rated capacity for such manufacturing processes as of October 1, 1984". (40 CFR 76.187(a))

#### **Item Number 3: Recalculation of Annual Pound Limit for the Site**

It is your understanding that new products which contain inadvertently generated PCBs can be manufactured at your Houston, Texas facility and that these new products would trigger a recalculation of the pound limit for the site. It is your belief that the rated production capacity of the new unit as of its construction date would be added to the rated pound capacity of the existing units (as of October 1, 1984) and then multiplied by 0.0025% to yield a new PCB pound limit for the manufacturing site under 40 CFR 761.187.

#### **Response to Item Number 3:**

You are incorrect in your understanding of the recalculation of your annual pound limit for the site. As stated above, reporting under 40 CFR 761.187 is triggered when PCBs in products leaving the site exceed 0.0025 percent of the site's rated capacity for such manufacturing processes as of October 1, 1984. So whether ISK creates new product or

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increases old product which contain PCBs from an excluded manufacturing process, reporting is required under 40 CFR 761.187 when you exceed by 0.0025 percent of your October 1, 1984 baseline rated capacity. Your October 1, 1984 rated capacity remains the constant by which you will annually calculate your need to report under 40 CFR 761.187. This October 1, 1984 rated capacity does not change based on any current changes in the site's amount of product that is manufactured and contains PCBs as a result of an excluded manufacturing process. ISK would have to report annually if the total amount of new product that contains inadvertently generated PCBs exceeds by 0.0025% your rated capacity as of October 1, 1984.

#### **Items Number 4, 5, & 6: Waste Generated from an Excluded Manufacturing Process**

You seek confirmation of your understanding that the term "waste" generated from an excluded manufacturing process for purposes of 40 CFR 761 applies at the point of generation of the waste as it exits the production unit for the last time. You further contend that consistent with the recycling exemption under RCRA (40 CFR 261.2(e)(1)) for waste that is returned to the original process from which it is generated, this type of legitimate recycling exemption applies to PCB waste generated from an excluded manufacturing process production facility. Further, it is your understanding that PCB waste which is reusable and is returned to the original process is exempt from regulation under 40 CFR 761 until it is removed from the process for purposes of disposal.

In Item number 5 you seek confirmation that if process waste is tested at the point of generation and found to contain less than 50 ppm PCBs it is not subject to the disposal requirements at 40 CFR 761.60. In addition, in Item Number 6, you seek to confirm that residues of greater than 50 ppm PCB waste that are contained within a process unit's dike wall, that are periodically washed down to a sump where they come in contact with other non-PCB solids and liquids from the process unit area are not considered PCB if the sump solids are tested and found to contain less than 50 ppm PCBs since the point of generation for the sump clean out waste is at the sump, when the solids are physically removed.

#### **Response to Item Numbers 4, 5, & 6:**

In general, PCB waste  $\geq 50$  ppm that is generated at any point in the chemical manufacturing process may not be returned to the process. It must be disposed of in accordance with the provisions of 40 CFR 761.60. There is no recycling exemption under the TSCA PCB regulations for inadvertently generated PCB waste  $\geq 50$  ppm in an excluded manufacturing process that mirrors RCRA's exemption under 40 CFR 261.2(e)(1). Therefore, any waste generated at any time in the excluded manufacturing process that is  $\geq 50$  ppm must be properly disposed of; not reused in the process. (If finalized as proposed, the PCB Disposal Amendments would allow the reuse of this material if it was decontaminated to below 2 ppm PCBs.) Process waste  $< 50$  ppm from an excluded manufacturing process is not subject to the disposal requirements of 40 CFR 761.60.

Process wastes  $\geq 50$  ppm that are washed down to a sump where they come in contact

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with non-PCB solids and liquids render all the sump solids and liquids  $\geq 50$  ppm PCB and subject to the disposal provisions of 40 CFR 761.60. 40 CFR 761.1(b) specifically states: "No provision specifying a PCB concentration may be avoided as a result of any (emphasis added) dilution, unless otherwise specifically provided." It is this "anti dilution" provision under the TSCA PCB regulations that makes all the sump solids and liquids, regardless of their original concentration, that come in contact with PCBs  $\geq 50$  ppm subject to the PCB waste disposal provisions of 40 CFR 761.60. The point at which you remove the waste from the sump is irrelevant.

If you have any further questions or comments concerning these issues, you may contact Tom Simons of my staff at 202-260-3991.

Sincerely,

Tony Baney, Chief  
Fibers and Organics Branch

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

MAR - 5 1998

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Jeffery K. Van Horne  
Environmental Engineer  
ISK Biosciences Corp.  
2239 Haden Road  
Houston, TX 77015

Dear Mr. Van Horne:

This is in response to your letter of October 29, 1997 in which you request an interpretation of the PCB regulations at 40 CFR part 761, in particular, your concerns focus on the management of wastes and products derived from an "excluded manufacturing process" as defined under 40 CFR 761.3. As background, your letter indicates that ISK operates two processes that have been in existence since prior to 1984, each of which qualify as an excluded manufacturing process, and for which you have submitted certification for the products pursuant to 40 CFR 761.185. Your letter also states that in the future you may need to increase production of one of the products and/or suspend production of one of the products. Your letter raises six "Items" for discussion, each of which will be summarized and responded to accordingly.

**Item Number 1: Reporting Criteria at 40 CFR 761.187**

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**Response to Item Number 1:**

The intent of the recordkeeping, certification, and reporting requirements under 40 CFR 761.185, 187, and 193 was to use this information to develop an enforcement strategy and compliance monitoring program as well as to track the amount of inadvertently generated PCBs



produced. ISK may continue to take advantage of the exclusions as an excluded manufacturer as long as the basic requirements of 40 CFR 761.1(b) are met, the definition of "excluded manufacturing process" at 761.3 is adhered to, and the provisions of 761.185, 187, and 193 are complied with as appropriate. Reporting data to EPA pursuant to the provisions of 40 CFR 761.187 should have no adverse consequences to ISK's business. EPA does not announce the receipt of the information, but the information is available for public review in the TSCA Public Docket.

#### **Item Number 2: Definition of "Site" at 40 CFR 761.187**

It is your understanding that the term "site" at 40 CFR 761.187 refers to a manufacturing facility which may contain several production units such as ISK's Houston, Texas facility. In determining the pound baseline for which reporting to the EPA is triggered, the total PCB pound baseline is calculated by taking the sum of the rated pound capacity as of October 1, 1984 of the two manufacturing processes (each which produce a product subject to the excluded manufacturing process exemption) and multiplying by 0.0025%. This calculated PCB pound amount remains as the baseline for reporting for the site, regardless of future increases or decreases in production. Further, it is your understanding that the PCB pound limit is site specific, not product or process specific.

#### **Response to Item Number 2:**

You are correct in your understanding of the term "site" and how to calculate whether you have exceeded the 1984 pound baseline for which reporting to EPA is triggered under 40 CFR 761.187. The PCB pound limit calculation is site specific and not process or product specific. It is based on the "total quantity of PCBs in products from excluded manufacturing processes leaving any manufacturing site in any calendar year, when such quantity exceeds 0.0025 percent of that site's rated capacity for such manufacturing processes as of October 1, 1984". (40 CFR 76.187(a))

#### **Item Number 3: Recalculation of Annual Pound Limit for the Site**

It is your understanding that new products which contain inadvertently generated PCBs can be manufactured at your Houston, Texas facility and that these new products would trigger a recalculation of the pound limit for the site. It is your belief that the rated production capacity of the new unit as of its construction date would be added to the rated pound capacity of the existing units (as of October 1, 1984) and then multiplied by 0.0025% to yield a new PCB pound limit for the manufacturing site under 40 CFR 761.187.

#### **Response to Item Number 3:**

You are incorrect in your understanding of the recalculation of your annual pound limit for the site. As stated above, reporting under 40 CFR 761.187 is triggered when PCBs in products leaving the site exceed 0.0025 percent of the site's rated capacity for such manufacturing processes as of October 1, 1984. So whether ISK creates new product or

increases old product which contain PCBs from an excluded manufacturing process, reporting is required under 40 CFR 761.187 when you exceed by 0.0025 percent of your October 1, 1984 baseline rated capacity. Your October 1, 1984 rated capacity remains the constant by which you will annually calculate your need to report under 40 CFR 761.187. This October 1, 1984 rated capacity does not change based on any current changes in the site's amount of product that is manufactured and contains PCBs as a result of an excluded manufacturing process. ISK would have to report annually if the total amount of new product that contains inadvertently generated PCBs exceeds by 0.0025% your rated capacity as of October 1, 1984.

#### **Items Number 4, 5, & 6: Waste Generated from an Excluded Manufacturing Process**

You seek confirmation of your understanding that the term "waste" generated from an excluded manufacturing process for purposes of 40 CFR 761 applies at the point of generation of the waste as it exits the production unit for the last time. You further contend that consistent with the recycling exemption under RCRA (40 CFR 261.2(e)(1)) for waste that is returned to the original process from which it is generated, this type of legitimate recycling exemption applies to PCB waste generated from an excluded manufacturing process production facility. Further, it is your understanding that PCB waste which is reusable and is returned to the original process is exempt from regulation under 40 CFR 761 until it is removed from the process for purposes of disposal.

In Item number 5 you seek confirmation that if process waste is tested at the point of generation and found to contain less than 50 ppm PCBs it is not subject to the disposal requirements at 40 CFR 761.60. In addition, in Item Number 6, you seek to confirm that residues of greater than 50 ppm PCB waste that are contained within a process unit's dike wall, that are periodically washed down to a sump where they come in contact with other non-PCB solids and liquids from the process unit area are not considered PCB if the sump solids are tested and found to contain less than 50 ppm PCBs since the point of generation for the sump clean out waste is at the sump, when the solids are physically removed.

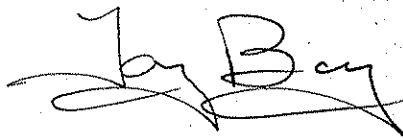
#### **Response to Item Numbers 4, 5, & 6:**

In general, PCB waste  $\geq 50$  ppm that is generated at any point in the chemical manufacturing process may not be returned to the process. It must be disposed of in accordance with the provisions of 40 CFR 761.60. There is no recycling exemption under the TSCA PCB regulations for inadvertently generated PCB waste  $\geq 50$  ppm in an excluded manufacturing process that mirrors RCRA's exemption under 40 CFR 261.2(e)(1). Therefore, any waste generated at any time in the excluded manufacturing process that is  $\geq 50$  ppm must be properly disposed of; not reused in the process. (If finalized as proposed, the PCB Disposal Amendments would allow the reuse of this material if it was decontaminated to below 2 ppm PCBs.) Process waste  $< 50$  ppm from an excluded manufacturing process is not subject to the disposal requirements of 40 CFR 761.60.

Process wastes  $\geq 50$  ppm that are washed down to a sump where they come in contact with non-PCB solids and liquids render all the sump solids and liquids  $\geq 50$  ppm PCB and subject to the disposal provisions of 40 CFR 761.60. 40 CFR 761.1(b) specifically states: "No provision specifying a PCB concentration may be avoided as a result of any (emphasis added) dilution, unless otherwise specifically provided." It is this "anti dilution" provision under the TSCA PCB regulations that makes all the sump solids and liquids, regardless of their original concentration, that come in contact with PCBs  $\geq 50$  ppm subject to the PCB waste disposal provisions of 40 CFR 761.60. The point at which you remove the waste from the sump is irrelevant.

If you have any further questions or comments concerning these issues, you may contact Tom Simons of my staff at 202-260-3991.

Sincerely,

A handwritten signature in black ink, appearing to read "Tony Baney". The signature is stylized with a large, looped "T" and a cursive "Baney".

Tony Baney, Chief  
Fibers and Organics Branch

# ISK BIOSCIENCES™

Certified Mail, Return Receipt # P 960 179 124

October 29, 1997

Mr. Tony Baney  
Chief of Fibers and Organics Branch  
Mail Code 7404  
United States Environmental Protection Agency  
401 M Street Southwest  
Washington D.C. 20460

**Subject: Request for Interpretation of PCB Regulations**

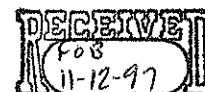
Dear Mr. Baney:

We have recently been in contact with the Toxic Substances Control Act (TSCA) Hot Line and were referred to Mr. Tom Simmons of your staff. We raised several issues regarding the management of wastes and products under the excluded manufacturing processes exemption of 40 CFR Part 71. Mr. Simmons suggested that we write you, requesting your response in writing regarding each of these issues.

I am providing you with some background information of our manufacturing site in Houston, Texas. Also, I am describing each issue and the management method which we are using for compliance. Based on our discussions with Mr. Simmons, it is our understanding that we are in compliance with the TSCA regulations regarding each issue. We will continue to manage each issue as described. If our understanding of the regulations is incorrect, please let us know.

**Background**

ISK Biosciences owns and operates a chemical manufacturing facility in Houston, Texas. At this site, ISK operates two processes, each of which make a chemical product which is covered under the excluded manufacturing process exemption as defined in 40 CFR §761.3. Both manufacturing processes have been in existence since prior to 1984. ISK Biosciences believes it is in full compliance with the excluded manufacturing process exemption for these products. Certifications for the products have been made under 40 CFR §761.185. Neither of the products can be economically produced without the incidental manufacture of Polychlorinated Biphenyls (PCBs). ISK Biosciences may, in the future, have the need to increase production of one of the



ISK Biosciences Corporation  
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P.O. Box 9637, Houston, Texas 77213, U.S.A.  
713/453-7281 • FAX: 713/450-6339

products and/or suspend production of one of the products.

**Item Number 1:**

Regarding 40 CFR §761.187, it is our understanding that the intent of the reporting criteria is to provide EPA with a means of accounting for major releases of inadvertent PCBs and for reassessing the PCB rules, if necessary. In establishing the reporting criteria, it is our understanding that it was not EPA's intent to limit production of products and/or the amount of inadvertently generated PCBs. Therefore, should ISK increase production of its' products and thus increase the amount of inadvertently generated PCBs over the established PCB pound limit for the Houston, Texas site, and report to EPA under 40 CFR §761.187, it is our understanding that no adverse consequences of making such notification to EPA will result to ISK's business, that no public announcements will be made by EPA regarding such notification, and that EPA may retain the information on file for data recordation and future assessments on the PCB rule.

Reference: Federal Register Volume 49 No. 133, Tuesday, July 10, 1984 page 28181, paragraph II.H.6.

**Item Number 2**

Regarding 40 CFR §761.187, it is our understanding that the term "site" refers to a manufacturing facility which may contain several production units such as ISK's Houston, Texas facility. In determining the PCB pound baseline for which reporting to EPA is triggered, the total pounds PCB baseline is calculated by taking the sum of the rated pound capacity as of October 1, 1984 of the two manufacturing processes (which each produce a product subject to the excluded manufacturing process exemption) and multiplying by .0025%. This calculated PCB pound amount remains as the baseline for reporting for the site, regardless of future production increases or suspensions of production. It is our understanding that the PCB pound limit is site specific, not process or product specific.

**Item Number 3**

With regard to Item Number 2 above, it is also our understanding that new products which contain PCBs can also be manufactured at our Houston, Texas facility. ISK believes that a new production unit would trigger a recalculation of the annual pound limit for the site. It is our understanding that the rated production capacity of the new unit as of its construction date would be added to the rated pound capacity of the existing units (as of October 1, 1984) then multiplied by .0025% to yield a new PCB pound limit for the manufacturing site under 40 CFR §761.187.

**Item Number 4**

Regarding waste generated from an "excluded manufacturing process exempted" production unit, it is our understanding that the definition of PCB subjecting such waste to regulation under 40 CFR 761 is applied at the point of generation of the waste, as it exits the production unit for the

last time. Consistent with the recycling exemptions of a solid waste under RCRA for waste that is returned to the original process from which it was generated, we believe that this type of legitimate recycling exemption applies to PCB waste generated from an excluded manufacturing process production facility. It is our understanding that PCB waste which is reusable and is returned to the original process is exempt from regulation under 40 CFR 761 until it is removed from the process for purposes of disposal.

**Item Number 5**

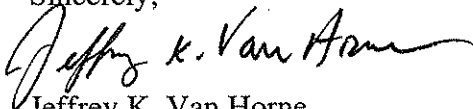
Regarding waste generated from an "excluded manufacturing process exempted" production unit, it is our understanding that the definition of PCB subjecting such waste to regulation under 40 CFR 761 is applied at the point of generation of the waste, as it exits the production unit. It is our understanding that: If a process waste is tested, at the point of generation, and found to contain <50 ppm PCB, it is not subject to the disposal requirements under 40 CFR 761.60.

**Item Number 6**

Regarding waste generated from an "excluded manufacturing process exempted" production unit, it is our understanding that the definition of PCB subjecting such waste to regulation under 40 CFR 761 is applied at the point of generation of the waste, as it exits the production unit. It is our understanding that residues of >50 ppm PCB waste that are contained within a process units dike wall, that are periodically washed down to a sump where they come into contact with other non PCB solids and liquids from the process unit area, are not considered PCB if the sump solids are tested and found to contain <50 ppm PCB. In this case, the process of generating a waste is the periodic clean out of a sump, therefore, the point of generation for the sump clean out waste is at the sump, when the solids are physically removed.

ISK appreciates the time that Mr. Simmons took to discuss these matters with us during our recent telephone conversation and your consideration of the issues we have presented in this letter. Mr. Simmons indicated that a two week to one month response time for this request may be required. Since some of these issues may have an immediate cost impact to our company and since all of the issues are important to the possible future expansion of our Houston, Texas site, we would greatly appreciate your timely response. If you have any questions regarding this request, please call me at (713) 450-6324.

Sincerely,



Jeffrey K. Van Horne  
Environmental Engineer  
ISK Biosciences Corporation